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Application No.	Ref.	Date
98 310 224.5-2116	N.75800 GCW	04.12.2000
Applicant: MARINE BIOTECHNOLOGY INSTITUTE CO., LTD.		

Communication pursuant to Article 96(2) EPC

The examination of the above-identified application has revealed that it does not meet the requirements of the European Patent Convention for the reasons enclosed herewith. If the deficiencies indicated are not rectified the application may be refused pursuant to Article 97(1) EPC.

You are invited to file your observations and insofar as the deficiencies are such as to be rectifiable, to correct the indicated deficiencies within a period

of 4 months

from the notification of this communication, this period being computed in accordance with Rules 78(2) and 83(2) and (4) EPC.

Amendments to the description, claims and drawings are to be filed where appropriate within the said period in **three copies** on separate sheets (Rule 36(1) EPC).

Failure to comply with this invitation in due time will result in the application being deemed to be withdrawn (Article 96(3) EPC).

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BRADBROOK D A
Primary Examiner
for the Examining Division

Enclosure(s): 4 page/s reasons (Form 2906)
D2: Appl.Environ.Microbiol., Vol.61, pp.1104-1109 (1995)

Registered Letter

The examination is being carried out on the **following application documents:**

Text for the Contracting States:
DE FR GB IT

Description, pages:

1-76 as originally filed

Claims, No.:

1-4 as originally filed

Drawings, sheets:

1/1 as originally filed

1. The following document is referred to in this communication; the numbering will be adhered to in the rest of the procedure:

   D1: Database WPI Week 9541 Derwent Publications Ltd., London, GB; AN 95-315932 XP002113794 'Identify detect microbe DNA gene sequence allow more accuracy define microbe strain species' & JP 07 213299 A (Kaiyo Biotechnology Kenkyusho KK; 15.08.95);

   D2: Yamamoto and Harayama, Appl.Environ.Microbiol., Vol.61, pp.1104-1109 (1995);

   D3: US-A-5 645 994 (Huang Wai Mun; 08.07.97);

   D4: WO 97 35970 A (Nippon Suisan Kaisha Ltd; 02.10.97).

   Document D2 is a journal publication, the content of which appears to correspond to that of the patent D1, and which has been cited by the applicant in the present description. A copy of the document D2 is annexed to the communication.

2. The present application does not meet the requirements of Article 52(1) EPC, because the subject-matter of claims 1-4 is not new in the sense of Article 54(1)

and (2) EPC.

Claim 1 is directed to a method for identifying a microorganism using PCR amplification, in which at least one of the primers "comprises sequence which codes for all or part of" one of the given amino acid sequences (a)-(l). Insofar as the smallest said part is not specified (and so may represent only one amino acid), this definition of the primer is so broad that it includes any primer used in such a method. For instance, in D4 the following primer is used for detecting and identifying Vibrio parahaemolyticus (see abstract):
TCC GCT TCG CGC TCA TCA ATA.
The first six nucleotides encode Ser-Ala, which are the first two residues in sequence a; this primer from D4 therefore falls under the scope of those defined in present claim 1, so that claim 1 is not novel over D4. As the primer definition in each of claims 2-4 is similarly broad, these claims are also not novel.

3. Should the applicant wish to overcome the above objection by narrower definition of the primers, the following matters should be considered.

4. D1 and D2 disclose a method for identification or detection of a microbe using the base sequence of the DNA gyrase gene. The sequence preferably encodes the region between two amino acid sequences corresponding to portions of sequences (a) and (c) respectively of the present claims (D1: abstract; D2: Fig.1). The primers for amplification are shown in D2 (Fig.1). Thus, claims 1-4 are not distinguished from D1 and D2 and are therefore not novel (Art.54(1) and (2) EPC).

5. D3 describes methods of identifying species in a sample based on pairs of consensus amino acid segments which flank variable segments of type II DNA topoisomerase (DNA gyrase). In one embodiment, DNA primers termed "universal primers" are used to amplify the variable or "signature" sequences (see abstract). One such primer shown in Figure 2 (segment 2: SEQ ID NO:101; see also claim 26) corresponds to an eight amino acid portion of sequence (d) of present claim 1. Therefore, D3 renders the subject-matter of claim 1 not novel (Art. 54(1) and (2) EPC).

6. The present application does not meet the requirements of Article 84 EPC in that

the scope of the claims is broader than justified by the description and drawings; therefore, the claims are not properly supported by the description as required by Article 84 EPC. The reasons therefor are the following:

According to the specification (p.5, 2nd full paragraph), the object of the present invention is to overcome some of the problems outlined (p.4, last para. - p.5, to end of 1st full paragraph). In particular, primers used by the authors in D2 amplify not only the gyrB gene, but also the parE gene in some bacteria. However, as the primers of D2 fall within the scope of those of the present claims (see above), clearly not all of the primers specified in the present claims provide a solution for overcoming such problems. Also, the number of possible primer sequences which would encode sequences (a)-(l) is so large that they would inevitably not all have the desired effect, namely specific amplification of the gyrB gene.

Claim 3 is further not supported (Art.84 EPC) in that clearly not every primer group is suitable for pairing with every other primer group: for instance a pairing of (b) with (l), or (h) with (e), or (f) with (j), would seem to be ineffectual for PCR.

7. It is unclear how the skilled person should choose, from the large number of possible permutations, a primer appropriate for analysis of a sample containing an unknown microorganism. In examples 1-11, amplification from known strains is carried out; example 12 uses an unknown strain, but the selection of the primers is not explained. It is advised (description: p.11, last 4 lines) that, as the amino acid sequences (a) to (l) are not conserved in all gyrB, primers should be selected appropriately; however, no further guidance is provided. Thus, it is considered to represent an undue burden on the part of the skilled person to determine which particular primers should be used for a particular analysis, so that the invention is not properly disclosed across its entire scope (Art.83 EPC).

8. The applicant is requested to file new claims which take account of the above comments.

The applicant is requested to effect the amendments by filing replacement pages for only those pages which have been amended. The description should be adapted to any new set of claims filed in response to this communication,

although unnecessary recasting of the description should be avoided. The applicant should also take account of the requirements of Rule 36(1) EPC. In particular, fair copies of the amended pages should be filed in triplicate. The applicant is asked to furnish in respect of every amendment an additional copy showing the hand-corrected original sheet.

The applicant is reminded that all amendments must be carried out under strictest observation of Article 123(2) EPC. In order to ascertain whether the new claims meet the requirements of Article 123(2), the applicant is requested to indicate, in the letter of reply, where a basis may be found, in the originally filed application, for each and every amendment made to the application.